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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,131	11/10/2000	Ronald B. Gartenhaus	056304.00000	4043

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HODGSON RUSS LLP
THE GUARANTY BUILDING
140 PEARL STREET
SUITE 100
BUFFALO, NY 14202-4040

EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
03/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/709,131	GARTENHAUS, RONALD B.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17,32,36,37 and 42-47* is/are pending in the application.

4a) Of the above claim(s) *14-17 and 42-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Gartenhaus

1. Applicant's response filed on 12/31/2008 is acknowledged. Claims 14-17, 32, 36, 37 and 42-47 are pending. Claims 1-13, 18-31, 33-35, 38-41 and 48 have been cancelled. Claims 14-17 and 42-47 have been withdrawn from consideration. Claim 32 has been amended.

2. Claims 32, 36, and 37 are under examination.

Objections Withdraws

3. The objection to claims 32, 36, 37, 40 and 41 for the recitation of the term MCT-1 as the sole means of identifying the polypeptide to which the claimed antibody binds is withdrawn in view of applicant's amendment to the claims.

Rejections Withdrawn

4. The rejection of claims 32, 37 and 48 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of applicant's amendment to the claims.

5. The rejection of claims 40 and 41 under 35 U.S.C. 112, first paragraph because of new matter is withdrawn in view of applicant's cancellation of the claims.

Rejections Maintained

Claim Rejections - 35 USC 101

6. The rejection of claims 32, 36, and 37 under 35 USC 101 because the claimed invention lacks patentable utility is maintained.

The response states that there is no articulated assertion on the record (and it has not been otherwise established by the examiner) that it is more likely than not that a person of ordinary skill in the art would consider that the presently claimed antibodies lack a substantial utility. In the Declaration of Dr. Gordon submitted by applicant, Dr. Gordon states that it was evident to him from the reference (Gartenhaus et al., A novel candidate oncogene, MCT-1, is involved in cell cycle progression, Cancer Res. 1998, 1: 4233-7) that antibodies to MCT-1 protein could have been useful for analyzing MCT-1 protein expression and localization in cells that exhibited deregulated growth, for determining whether MCT-1 mRNA expression was correlated with protein expression and for evaluating compounds for affects on the expression of MCT-1 protein. Dr. Gordon states that based on the disclosed properties of MCT-1 protein which include a predicted structural homology between MCT-1 protein and cyclin, MCT-1 overexpression decreases duration of the G1/S phase of the cell cycle, and MCT-1 has transforming ability in vitro, it was evident to him that MCT-1 was involved in unregulated cell proliferation of the type common to many malignancies.

Applicant's arguments have been carefully considered but are not persuasive. The Declaration of Dr. Gordon has been carefully reviewed but is insufficient to overcome the rejection. The specification asserts that the MCT-1 can be used for diagnosis of tumor by comparing MCT-1 expression in a tumor cell and MCT-1 expression in a non-tumor cell, wherein a difference in expression is indicative that the

cell is a tumor cell (paragraph bridging pages 4-5). The specification discloses that MCT-1 gene is amplified in the HUT 78 cell line and that in NIH 3T3 cells transfected with a MCT-1 construct, which constitutively expressed MCT-1 protein, the G1 phase of the cell cycle was shortened and promotes anchorage independent growth. However, when primary cancer samples were assayed from 40 CTCL patients and 20 chronic lymphocytic leukemia patients, MCT-1 amplification was not detected in any of these primary cancer samples (see page 40, lines 14-23). Applicant's submitted publication of Prosniak et al. (Cancer Res. 1998, 1: 4233-7) discloses the same results (see page 4237, column 2, paragraph 2). As indicated in the previous office action mailed on 7/29/08, the art recognizes that the characteristics of cultured cell lines generally differ significantly from the characteristics of the primary tumor. Even though the instant inventors found MCT-1 gene to be amplified in a cultured cell line (HUT78 cell line) with concomitant overexpression of protein, Pollack et al (Nature Genetics, 1999, 23:41-46) specifically teaches that in an assay of 3195 genes it was found that most genes in cancer cells are not either amplified or overexpressed (see Figure 5, page 44) and that most highly expressed genes are not amplified, and not all amplified genes are highly expressed (p. 45, col 1). Therefore, the mere observation of MCT-1 amplification in a single cell line, i.e. HUT78 cell line (obtained from a patient afflicted with Sezary syndrome) would not be considered sufficient for establishing a correlation between MCT-1 protein expression and tumor presence, especially in view of the negative results from the primary tumors. Based on the disclosure of the instant specification and the teachings of the prior art, one skilled in the art would reasonably conclude that it

is more likely than not that a person of ordinary skill in the art would consider that the presently claimed antibodies lack a substantial utility. Dr. Gordon's opinion appears to be partly based on the predicted structural homology between MCT-1 protein and cyclin (see the Declaration, paragraph 3). It is noted that the claimed MCT-1 protein only has a sequence identity of 32% over a 58 amino acid stretch with the COOH-terminal domain of cyclin H (see submitted publication of Prosniak et al., page 4235, column 2, paragraph 3). As indicated in the previous office action mailed on 8/7/2006, it is known in the art that the relationship between the amino acid sequence of a protein (polypeptide) and its tertiary structure are not well understood and are not predictable. There is no recognition in the art that sequence with identity predicts biological function. It is known in the art that even single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function. Thus in the instant case, one of skill in the art would not be able to predict the function of the claimed protein based on its 32% sequence identity to a 58 amino acid stretch with the COOH-terminal domain of cyclin H still. Dr. Gordon's opinion appears to be further based on the observation that the MCT-1 overexpression decreases duration of the G1/S phase of the cell cycle and MCT-1 has transforming ability in vitro. Such observation is insufficient to support a substantial utility of the claimed MCT-1 protein because applicant's asserted substantial utility based on such observation is to diagnosing a cancer. As indicated above, the specification discloses when primary cancer samples were assayed from 40 CTCL patients and 20 chronic lymphocytic leukemia patients, MCT-1 amplification was not detected in any of these primary cancer

samples (see page 40, lines 14-23). Addition work must be done to understand the biological functions of MCT-1 in tumor formation and progression. MPEP 2107.01 states that "a "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities". Thus, the polypeptides to which the claimed antibody binds do not have substantial utility. Since the asserted utility of the claimed antibody is for assaying for or identifying the polypeptide of SEQ ID NO:8, since the polypeptide of SEQ ID NO:8 does not have substantial utility for the reasons set forth above, the claimed antibody also does not have substantial utility.

Because of these reasons, the rejection is deemed proper and therefore maintained.

7. The rejection of claims 32, 36, and 37 under 35 USC 112, first paragraph as failing to comply with the enablement requirement is maintained.

This rejection is maintained for the same reasons as set forth above for 35 USC 101 rejection.

Conclusion

8. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
2/20/2009

/Christopher H Yaen/
Primary Examiner, Art Unit 1643